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INTERNATIONAL SEARCHING AUTHORITY

To:

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PCT

WRITTEN OPINION OF THE INTERNATIONAL SEARCHING AUTHORITY (PCT Rule 43bis.1)

Date of mailing
(day/month/year) see form PCT/ISA/210 (second sheet)

Applicant's or agent's file reference
see form PCT/ISA/220

FOR FURTHER ACTION
See paragraph 2 below

International application No.
PCT/IL2006/001291

International filing date (day/month/year)
09.11.2006

Priority date (day/month/year)
09.11.2005

International Patent Classification (IPC) or both national classification and IPC
INV. G01T1/161 G01T1/166 G01T1/29

Applicant
SPECTRUM DYNAMICS LLC

1. This opinion contains indications relating to the following items:

- ☒ Box No. I Basis of the opinion
- ☐ Box No. II Priority
- ☒ Box No. III Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
- ☒ Box No. IV Lack of unity of invention
- ☒ Box No. V Reasoned statement under Rule 43bis.1(a)(i) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
- ☐ Box No. VI Certain documents cited
- ☐ Box No. VII Certain defects in the international application
- ☐ Box No. VIII Certain observations on the international application

2. FURTHER ACTION

If a demand for international preliminary examination is made, this opinion will usually be considered to be a written opinion of the International Preliminary Examining Authority ("IPEA") except that this does not apply where the applicant chooses an Authority other than this one to be the IPEA and the chosen IPEA has notified the International Bureau under Rule 66.1bis(b) that written opinions of this International Searching Authority will not be so considered.

If this opinion is, as provided above, considered to be a written opinion of the IPEA, the applicant is invited to submit to the IPEA a written reply together, where appropriate, with amendments, before the expiration of 3 months from the date of mailing of Form PCT/ISA/220 or before the expiration of 22 months from the priority date, whichever expires later.

For further options, see Form PCT/ISA/220.

3. For further details, see notes to Form PCT/ISA/220.

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Date of completion of
this opinion

see form
PCT/ISA/210

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**WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITY**

International application No.
PCT/IL2006/001291

Box No. I Basis of the opinion

1. With regard to the **language**, this opinion has been established on the basis of:
 - ☒ the international application in the language in which it was filed
 - ☐ a translation of the international application into , which is the language of a translation furnished for the purposes of international search (Rules 12.3(a) and 23.1 (b)).
2. With regard to any **nucleotide and/or amino acid sequence** disclosed in the international application and necessary to the claimed invention, this opinion has been established on the basis of:
 - a. type of material:
 - ☐ a sequence listing
 - ☐ table(s) related to the sequence listing
 - b. format of material:
 - ☐ on paper
 - ☐ in electronic form
 - c. time of filing/furnishing:
 - ☐ contained in the international application as filed.
 - ☐ filed together with the international application in electronic form.
 - ☐ furnished subsequently to this Authority for the purposes of search.
3. ☐ In addition, in the case that more than one version or copy of a sequence listing and/or table relating thereto has been filed or furnished, the required statements that the information in the subsequent or additional copies is identical to that in the application as filed or does not go beyond the application as filed, as appropriate, were furnished.
4. Additional comments:

Box No. III Non-establishment of opinion with regard to novelty, inventive step and industrial applicability

The questions whether the claimed invention appears to be novel, to involve an inventive step (to be non obvious), or to be industrially applicable have not been examined in respect of

☐ the entire international application

☒ claims Nos. 94-130, 132, 133

because:

☐ the said international application, or the said claims Nos. relate to the following subject matter which does not require an international search (*specify*):

☐ the description, claims or drawings (*indicate particular elements below*) or said claims Nos. are so unclear that no meaningful opinion could be formed (*specify*):

☐ the claims, or said claims Nos. are so inadequately supported by the description that no meaningful opinion could be formed (*specify*):

☒ no international search report has been established for the whole application or for said claims Nos. 94-130, 132, 133

☐ a meaningful opinion could not be formed without the sequence listing; the applicant did not, within the prescribed time limit:

☐ furnish a sequence listing on paper complying with the standard provided for in Annex C of the Administrative Instructions, and such listing was not available to the International Searching Authority in a form and manner acceptable to it.

☐ furnish a sequence listing in electronic form complying with the standard provided for in Annex C of the Administrative Instructions, and such listing was not available to the International Searching Authority in a form and manner acceptable to it.

☐ pay the required late furnishing fee for the furnishing of a sequence listing in response to an invitation under Rules 13*ter*.1(a) or (b).

☐ a meaningful opinion could not be formed without the tables related to the sequence listings; the applicant did not, within the prescribed time limit, furnish such tables in electronic form complying with the technical requirements provided for in Annex C-*bis* of the Administrative Instructions, and such tables were not available to the International Searching Authority in a form and manner acceptable to it.

☐ the tables related to the nucleotide and/or amino acid sequence listing, if in electronic form only, do not comply with the technical requirements provided for in Annex C-*bis* of the Administrative Instructions.

☒ See Supplemental Box for further details

**WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITY**

International application No.
PCT/IL2006/001291

Box No. IV Lack of unity of invention

1. ☒ In response to the invitation (Form PCT/ISA/206) to pay additional fees, the applicant has, within the applicable time limit:
- ☐ paid additional fees
 - ☐ paid additional fees under protest and, where applicable, the protest fee
 - ☐ paid additional fees under protest but the applicable protest fee was not paid
 - ☒ not paid additional fees
2. ☐ This Authority found that the requirement of unity of invention is not complied with and chose not to invite the applicant to pay additional fees.
3. This Authority considers that the requirement of unity of invention in accordance with Rule 13.1, 13.2 and 13.3 is
- ☐ complied with
 - ☒ not complied with for the following reasons:
see separate sheet
4. Consequently, this report has been established in respect of the following parts of the international application:
- ☐ all parts.
 - ☒ the parts relating to claims Nos. 1-93, 131

Box No. V Reasoned statement under Rule 43*bis*.1(a)(i) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Statement

Novelty (N)	Yes: Claims	<u>1-93, 131</u>
	No: Claims	
Inventive step (IS)	Yes: Claims	<u>1-93, 131</u>
	No: Claims	
Industrial applicability (IA)	Yes: Claims	<u>1-93, 131</u>
	No: Claims	

2. Citations and explanations

see separate sheet

Re Item IV.

This Authority considers that there are 6 inventions covered by the claims indicated as follows:

Group I (claims 1-93, 131)

A method of dynamic SPECT data acquisition and a dynamic SPECT camera characterised by the timing mechanism enabling time-binning of radioactive emissions to time periods not greater than 30 seconds and an acquisition time for a tomographic reconstruction image of 300 seconds and an intracorporeal dynamic SPECT camera.

Group II (claim 94)

A dynamic SPECT camera of short damping time.

Group III (claims 95-103)

A stationary SPECT camera.

Group IV (claims 104, 105, 132)

A dynamic SPECT camera for time binning at dynamically varying time-bin lengths.

Group V (claims 106-116, 133)

A method and a dynamic SPECT camera for dynamically determining a spectral energy bin for each detecting unit.

Group VI (claims 117-130)

A method for anatomic construction of voxels.

The reasons for which the inventions are not so linked as to form a single general inventive concept, as required by Rule 13.1 PCT, are as follows:

The prior art has been identified as document

D1 : US 6 242 743 B1 (DEVITO RAYMOND P [US] ET AL) 5 June 2001 (2001-06-05)

and discloses

a dynamic SPECT camera (fig. 2) with an overall structure (fig. 2, ring), which defines proximal and distal ends with respect to a body; a first plurality of assemblies (fig. 2, 22), arranged on the overall structure, forming an array of the assemblies (fig. 2, ring, col. 15, lines 33-38), each assembly comprising: a second plurality of detecting units (fig. 2, 24, col. 15, lines 33-38), each detecting unit including: a single-pixel detector, for detecting radioactive emissions (col. 15, lines 47-55); and a dedicated collimator, attached to the single-pixel detector, at the proximal end thereof, for defining a solid collection angle for the detecting unit (fig. 2, 42, col. 19, lines 5-17); and an assembly motion provider, configured for providing the assembly with individual assembly motion with respect to the overall structure (fig. 2, 25, col. 17, lines 56-60), during the acquisition of radioactive-emission data for a tomographic image; a timing mechanism, in communication with each single-pixel detector, configured for enabling time-binning of the radioactive emissions impinging upon each single-pixel detector (fig. 11); and a position-tracker, configured for providing information on the position and orientation of each detecting unit, with respect to the overall structure, substantially at all times, during the individual motion (fig. 2, 40, col. 18, lines 53-59, fig. 11), the dynamic SPECT camera being configured for acquiring a tomographic reconstruction image of a region of interest of about 15 X 15 X 15 cubic centimeters (implicitly, breast imaging, heart imaging), at a spatial resolution of at least 10 X 10 X 10 cubic millimeter (col. 19, lines 18-38).

It follows that the following technical features make a contribution over the prior art and can be considered as special technical features within the meaning of Rule 13.2 PCT:

The timing mechanism enabling time-binning of radioactive emissions to time periods not greater than 30 seconds and an acquisition time of 300 seconds.

The problem solved by these special technical features can therefore be construed as:

Finding a compromise between identifying real coincident events and achieving a high detection signal.

The special technical feature of group I, as defined in Rule 13.2 PCT, therefore is:

The timing mechanism enabling time-binning of radioactive emissions to time periods not greater than 30 seconds and an acquisition time of 300 seconds.

Group II (claim 94) yields the non-disclosed (by the prior art document D1) potential special technical feature of:

A braking mechanism.

The problem to be solved by this claim could thus be said to reduce mechanical vibrations which might interfere with the data acquisition.

The special technical feature of group II not known from the above mentioned prior art, is:

A braking mechanism.

Group III (claims 95-103) yields the non-disclosed (by the prior art document D1) potential special technical features of:

A stationary SPECT camera with an assembly motion provider providing the assembly with motion prior to the acquisition of data, acquiring tomographic reconstruction of a region of interest while stationary for the whole duration of the tomographic image acquisition.

The problem to be solved by these claims could thus be said to determine a region of interest during a pre-scan.

The special technical feature of group III, not known from the above mentioned prior art, is:

A stationary SPECT camera with an assembly motion provider providing the assembly with motion prior to the acquisition of data, acquiring tomographic reconstruction of a region of interest while stationary for the whole duration of the tomographic image acquisition.

Group IV (claims 104, 105, 132) yields the non-disclosed (by the prior art document D1)

potential special technical features of:

A timing mechanism for time binning to time bins of dynamically varying time-bin lengths.

The problem to be solved by these claims could thus be said to compensate for the uptake curve of a radiopharmaceutical as well as for different parts of cardiac cycles.

The special technical feature of group IV, not known from the above mentioned prior art, is:

A timing mechanism for time binning to time bins of dynamically varying time-bin lengths.

Group V (claims 106-116, 133) yields the non-disclosed (by the prior art document D1) potential special technical features of:

A selection mechanism for enabling a selection of a spectral energy bin to be used for each detecting unit and a lookup system of recommended spectral energy bin values which is configured for dynamically determining the spectral energy bin for each detecting unit.

The problem to be solved by these claims could thus be said to eliminate contributions from other radiopharmaceuticals.

The special technical feature of group V, not known from the above mentioned prior art, is:

A selection mechanism for enabling a selection of a spectral energy bin to be used for each detecting unit and a lookup system of recommended spectral energy bin values which is configured for dynamically determining the spectral energy bin for each detecting unit.

Group VI (117-130) yields the non-disclosed (by the prior art document D1) potential special technical features of:

A method for anatomic construction of voxels with constructing an anatomic system of voxels in which the voxel boundaries are aligned with boundaries of structural objects of the region of interest, performing radioactive-emission imaging and reconstruction utilizing the anatomic system of voxels.

The problem to be solved by these claims could thus be said to avoid a smearing effect if different tissue types appear in a same voxel.

The special technical feature of group VI, not known from the above mentioned prior art, is:

A method for anatomic construction of voxels with constructing an anatomic system of voxels in which the voxel boundaries are aligned with boundaries of structural objects of the region of interest, performing radioactive-emission imaging and reconstruction utilizing the anatomic system of voxels.

From the above, it would seem that there are no technical features in the claimed inventions, which can be seen as common or corresponding special technical features within the meaning of Rule 13.2 PCT.

In determining a possible relationship between these 6 subjects, such as a common inventive concept, it has been found that the timing mechanism enabling time-binning of radioactive emissions to time periods not greater than 30 seconds and an acquisition time of 300 seconds does not contribute to the aims of:

- a) reducing mechanical vibrations which might interfere with the data acquisition,
- b) determining a region of interest during a pre-scan,
- c) compensating for the uptake curve of a radiopharmaceutical as well as for different parts of cardiac cycles,
- d) eliminating contributions from other radiopharmaceuticals,
- e) avoiding a smearing effect if different tissue types appear in a same voxel.

Furthermore, neither

- a) a braking mechanism, nor
- b) a stationary SPECT camera with an assembly motion provider providing the assembly with motion prior to the acquisition of data, acquiring tomographic reconstruction of a region of interest while stationary for the whole duration of the tomographic image acquisition,
- c) a timing mechanism for time binning to time bins of dynamically varying time-bin lengths, nor
- d) a selection mechanism for enabling a selection of a spectral energy bin to be used for each detecting unit and a lookup system of recommended spectral energy bin values which is configured for dynamically determining the spectral energy bin for each detecting unit, nor
- e) a method for anatomic construction of voxels with constructing an anatomic system of voxels in which the voxel boundaries are aligned with boundaries of structural objects of the region of interest, performing radioactive-emission imaging and reconstruction utilizing the anatomic system of voxels,

does contribute to the aim of finding a compromise between identifying real coincident events and achieving a high detection signal.

The only common concept to be found for some of the groups (groups I, II, IV, V) is a dynamic SPECT camera but this is known from document D1.

Furthermore, there are no further features available by means of which a relationship between the subjects of the 6 different sets of claims may be established.

Consequently, neither the objective problem underlying the subjects of the 6 claimed inventions, nor their solutions defined by the special technical features allow for a relationship to be established between the said inventions.

In conclusion, therefore, the 6 groups of claims are not linked by common or corresponding special technical features and define 6 different inventions not linked by a single general inventive concept. Hence, the application does not meet the requirements of Unity of Invention as defined in Rule 13.1 PCT.

Re Item V.

Further reference is made to the following documents:

D2 : GB 2 031 142 A (SHAW R) 16 April 1980 (1980-04-16)

D3 : AOI T ET AL: "Absolute quantitation of regional myocardial blood flow of rats using dynamic pinhole SPECT" 2002 IEEE NUCLEAR SCIENCE SYMPOSIUM CONFERENCE RECORD. / 2002 IEEE NUCLEAR SCIENCE SYMPOSIUM AND MEDICAL IMAGING CONFERENCE. NORFOLK, VA, NOV. 10 - 16, 2002, IEEE NUCLEAR SCIENCE SYMPOSIUM CONFERENCE RECORD, NEW YORK, NY : IEEE, US, vol. VOL. 3 OF 3, 10 November 2002 (2002-11-10), pages 1780-1783, XP010663867 ISBN: 0-7803-7636-6

D4 : US 2004/204646 A1 (NAGLER MICHAEL [IL] ET AL) 14 October 2004 (2004-10-14)

FIRST INVENTION (CLAIMS 1-93, 131)

1 CONCISENESS & CLARITY (Art. 6 PCT)

- 1.1 The application does not meet the requirements of Article 6 PCT, because **claims 1** and **73** are not concise.
- 1.2 The present set of claims comprises more than one independent claim in the same category, namely independent device claims 1 and 73. These claims appear to relate effectively to the same subject-matter for which protection is sought. The aforementioned claims therefore lack conciseness and clarity. Moreover, the lack of clarity of the claims as a whole arises, since the plurality of independent claims makes it difficult, if not impossible, to determine the matter for which protection is sought, placing an undue burden on others seeking to establish the extent of the protection and as such do not meet the requirements of Art 6 PCT and PCT/GL/ISPE/1/5.42.

2 INDEPENDENT CLAIM 1

Clarity Art. 6 PCT

- 2.1 **Claim 1** does not meet the requirements of Article 6 PCT in that the matter for which protection is sought is not clearly defined. The claim attempts to define the subject-matter in terms of the result to be achieved, which merely amounts to a statement of the underlying problem, without providing the technical features necessary for achieving this result.

Novelty, Inventive Step Art. 33 (2&3)

- 2.2 The document D1 is regarded as being the closest prior art to the subject-matter of claim 1, and shows (the references in parentheses applying to this document):

a dynamic SPECT camera (fig. 2) with an overall structure (fig. 2, ring), which defines proximal and distal ends with respect to a body; a first plurality of assemblies (fig. 2, 22), arranged on the overall structure, forming an array of the assemblies (fig. 2, ring, col. 15, lines 33-38), each assembly comprising: a second plurality of detecting units (fig. 2, 24, col. 15, lines 33-38), each detecting unit including: a single-pixel detector, for detecting radioactive emissions (col. 15, lines 47-55); and a dedicated collimator, attached to the single-pixel detector, at the proximal end thereof, for defining a solid collection angle for the detecting unit (fig. 2, 42, col. 19, lines 5-17); and an assembly motion provider, configured for providing the assembly with individual assembly motion with respect to the overall structure (fig. 2, 25, col. 17, lines 56-60), during the acquisition of radioactive-emission data for a tomographic image; a timing mechanism, in communication with each single-pixel detector, configured for enabling time-binning of the radioactive emissions impinging upon each single-pixel detector (fig. 11); and a position-tracker, configured for providing information on the position and orientation of each detecting unit, with respect to the overall structure, substantially at all times, during the individual motion (fig. 2, 40, col. 18, lines 53-59, fig. 11), the dynamic SPECT camera being configured for acquiring a tomographic reconstruction image of a region of interest of about 15 X 15 X 15 cubic centimeters (implicitly, breast imaging, heart imaging), at a spatial resolution of at least 10 X 10 X 10 cubic millimeter (col. 19, lines 18-38).

- 2.3 The subject-matter of claim 1 therefore differs from this known dynamic SPECT in that the time periods for the time binning are not greater than substantially 30 seconds and the acquisition time is 300 seconds.
- 2.4 Furthermore, the above mentioned lack of clarity notwithstanding, the subject-matter of claim 1 is therefore novel (Article 33(2) PCT).
- 2.5 The problem to be solved by the present invention may therefore be regarded as finding a compromise between identifying real coincident events and achieving a high detection signal.
- 2.6 Furthermore, the above mentioned lack of clarity notwithstanding, the solution to this problem proposed in claim 1 of the present application seems to involve an inventive step (Article 33(3) PCT) for the following reasons: Document D1 does not disclose or suggest the time-binning with periods not greater than 30 seconds nor an acquisition time of 300 seconds. Although the dynamic SPECT cameras of documents D2 and D3 disclose a time binning with periods of 10 seconds (D2, abstract) and 10 milliseconds (D3, page 4, lines 48-53), they do not however achieve the spatial resolution of the present application. Even if the skilled person would consider combining D2 or D3 with D1, it would not be obvious that the desired resolution of 10x10x10 cubic millimeter would be achieved, because, the time periods, the acquisition time and the spatial resolution are linked and dependent on each other.

3 INDEPENDENT CLAIM 131

- 3.1 The same reasoning as in section 2 applies, *mutatis mutandis*, to the subject-matter of the corresponding independent **claim 131**, which therefore seems also inventive.

4 INDEPENDENT CLAIM 73

Clarity Art. 6 PCT

- 4.1 **Claim 73** does not meet the requirements of Article 6 PCT in that the matter for which protection is sought is not clearly defined. The claim attempts to define the subject-matter in terms of the result to be achieved, which merely amounts to a statement of the underlying problem, without providing the technical features necessary for achieving this result.

Furthermore, it is not clear in claim 73 to what the motion provider provides motion.

Novelty, Inventive Step Art. 33 (2&3)

- 4.2 The document D4 is regarded as being the closest prior art to the subject-matter of claim 73, and discloses an intracorporeal dynamic SPECT camera with an overall structure, an assembly, arranged along a length of the overall structure, with a plurality of detecting units, each detecting unit including a single-pixel detector for detecting radioactive emissions and a dedicated collimator, attached to the single-pixel detector, at the proximal end thereof with respect to a region of interest, for defining a solid collection angle for the detecting unit, and a motion provider, a timing mechanism and a position tracker (see the passages cited in the search report). Document D4 does not disclose that the timing mechanism is configured for enabling time-binning of the radioactive emissions impinging upon each single-pixel detector time periods not greater than 30 seconds nor that the intracorporeal dynamic SPECT camera is configured for acquiring a tomographic reconstruction image of the region of interest of about 10x10x10 cubic centimeters and a spatial resolution of at least 10x10x10 cubic millimeters during an acquisition period of 30 seconds.
- 4.3 Furthermore, the above mentioned lack of clarity notwithstanding, the subject-matter of claim 73 is therefore novel (Article 33(2) PCT).
- 4.4 The problem to be solved by the present invention may therefore be regarded as finding a compromise between identifying real coincident events and achieving a high detection signal.
- 4.5 Furthermore, the above mentioned lack of clarity notwithstanding, the solution to this problem proposed in claim 73 of the present application is considered inventive

(Article 33(3) PCT) for the following reasons: Document D4 does not disclose or suggest the time-binning with periods not greater than 30 seconds nor an acquisition time of 30 seconds. None of the other prior art documents involving intracorporeal SPECT cameras suggest specific time periods or acquisition times. The skilled person would therefore not consider combining the teaching of one of these documents with D4.

5 DEPENDENT CLAIMS

- 5.1 **Claims 2-72** and **74-93** are dependent on claim 1 respectively claim 73 and as such also meet the requirements of the PCT with respect to novelty and inventive step.